



ZephyrTM

Patient Positioning and Transfer System

Model XL User Manual

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800142 REV B

This manual contains the latest information at the time of publication. Diacor, Inc. reserves the right to revise this manual without notice.

INTENDED USE

The Zephyr XL Patient Positioning and Transfer System is indicated to aid in the support, positioning, and transfer of a patient for procedures involving imaging, including MRI, and external beam radiation therapy treatment with electrons, photons or protons, as well as other procedures requiring transfer of a patient.

The Zephyr XL is intended for use only by physicians qualified in imaging and/or experienced in patient set up for planning or treatment, or by therapists at the specific direction of such qualified physicians.

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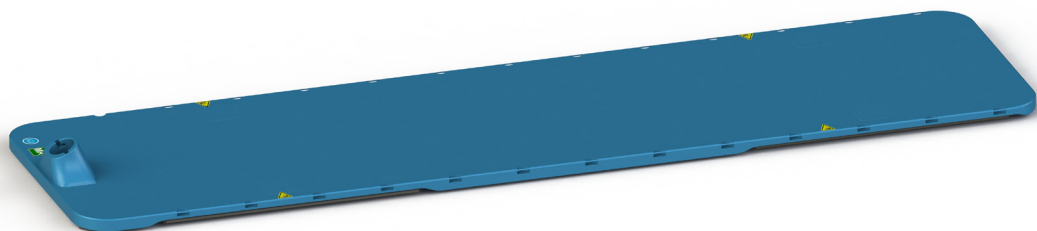


Figure 1.1 Diacor Zephyr XL Patient Positioning and Transfer System Base Board

TABLE OF CONTENTS

INTRODUCTION	1
GENERAL DESCRIPTION	5
2.1 GENERAL	5
2.2 FEATURES	5
2.2.1 Patient Transfer Base Board	5
2.2.1.1 Air Pads	5
2.2.1.2 Air Hose Connection	6
2.2.2 Zephyr XL Air Blower and Hose	6
2.2.2.1 Power Cord/Handheld Blower Control	6
2.2.2.2 ON/OFF Switch	8
2.2.2.3 Flexible Hose	8
2.2.2.4 Quick Turn Hose Connection	8
UNPACKING, INSTALLATION, USE	9
3.1 GENERAL	9
3.2 UNPACKING AND INSPECTION	9
3.3 INSTALLATION	9
3.4 USE	9
3.4.1 Pinch Points	11
SERVICING	13
4.1 GENERAL	13
4.2 CLEANING	13
4.3 PERIODIC MAINTENANCE	13
4.3.1 Air Blower Filter	13
4.4 HANDLING AND STORAGE	13
WARRANTY	15
5.1 GENERAL	15
5.2 WARRANTY DISCLAIMERS	15

5.3	WARRANTY PERFORMANCE	15
	TECHNICAL INFORMATION	17
6.1	GENERAL	17
6.2	SPECIFICATIONS	17
6.3	DIACOR BASEBOARD ATTENUATION MEASUREMENTS	17

SECTION

INTRODUCTION

1

The Zephyr XL Patient Positioning and Transfer System is used to aid in the support, positioning, and transfer of a patient for procedures involving Magnetic Resonance Imaging (MRI), Computed Tomography Imaging (CTI), Positron Emission Tomography (PET) imaging, Diagnostic X-ray Imaging (DXI), Radiation Therapy (RT) treatment by Medical Linear Accelerator or Charged Particle Accelerator and other procedures requiring transfer of a patient.

The Zephyr XL Patient Positioning and Transfer System consists of a rigid “MR Safe” Kevlar/Epoxy base board measuring 198.12cm x 53.01cm x 2.54cm (including pads). The underside of the base board has four perforated lift pads.

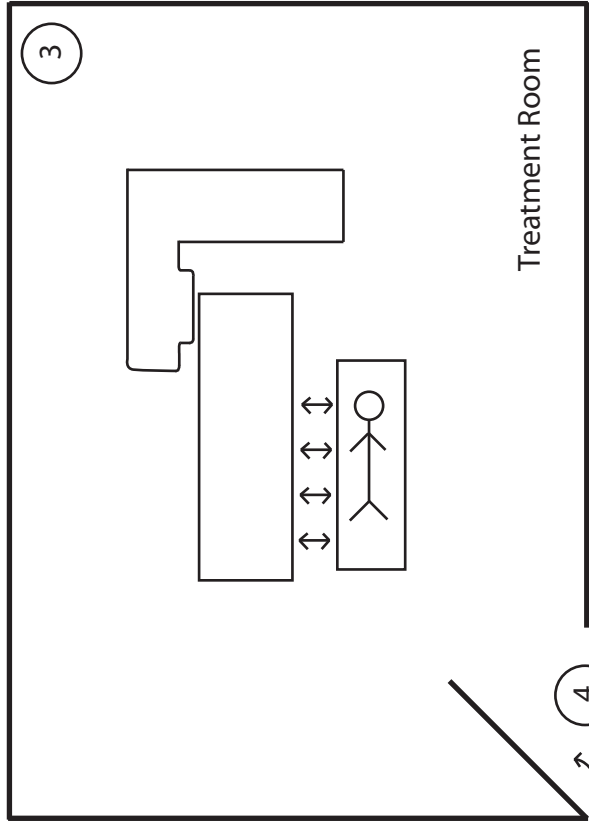
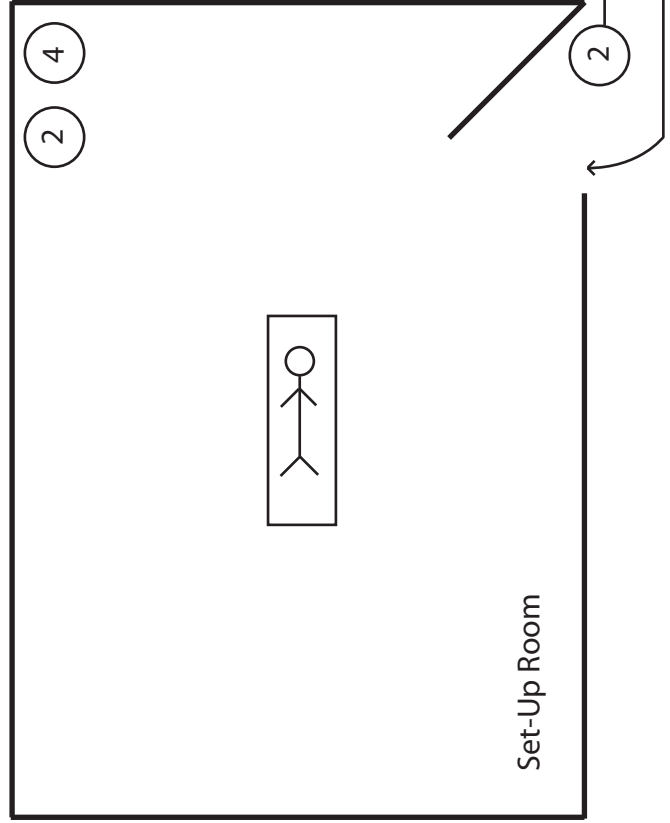
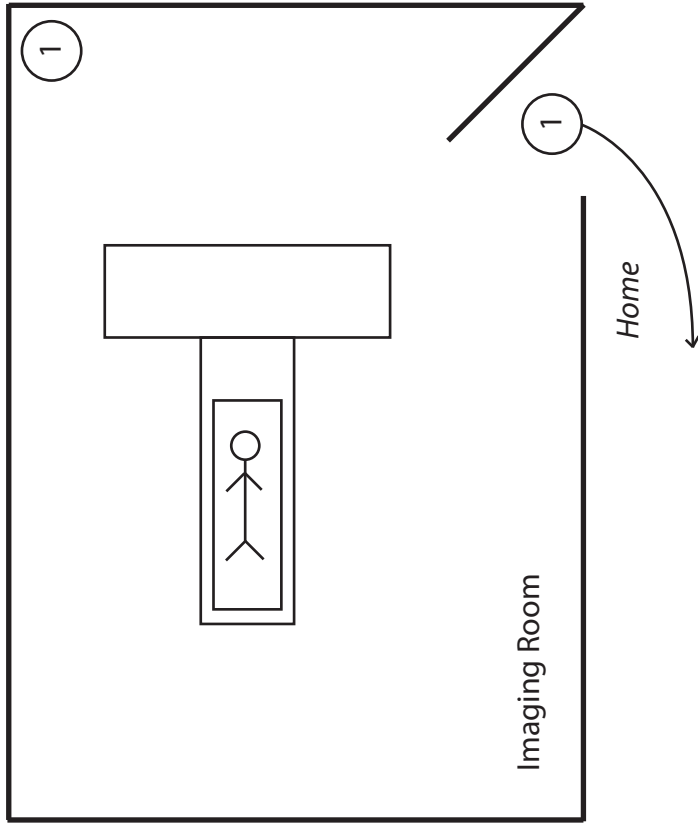
The Zephyr XL Patient Positioning and Transfer System utilizes forced air as a low-friction bearing to transfer patients from one flat surface to another, eliminating the need to manually lift the patient. The forced air is provided by an accessory air blower through a 10 foot length of flexible hose connected to the base board. The air is then routed to the perforated lift pads on the underside of the base board. When being used in MR, an extended flexible hose of 30 feet is available upon request, to position the “MR Unsafe” blower unit outside an MR imaging room, and continue to remain connected.

The base board is placed on a flat-surfaced wheeled stretcher (also available from Diacor). The base board is capable of attachment of various commercially available patient support and positioning accessories, utilized for imaging and treatment. The positioning aids, if required by the user, are placed upon and attached to the base board. The patient is then positioned on the base board with positioning aids, if applicable. The wheeled stretcher is then rolled to the procedure room and placed against the imaging or treatment table.

The patient is transferred to the imaging or treatment table by activating the blower. As the blower supplies air to the lift pads, the pads generate a nominal lift of 1 centimeter to the base board. This lift enables the base board to be moved from one flat surface to another with ease by two persons. The medical staff guides the base board and the patient to the position desired.

The base board is aligned with the index locations if available in the table. The blower is then deactivated and the base board settles on the flat supporting surface. The patient is then imaged or treated as required. During the procedure, the base board will function as an accessory to support and position the patient utilizing any non-Diacor positioning aids required by and supplied by the medical staff.

After the procedure, the blower is activated and the base board and patient are transferred to the wheeled stretcher. The blower is then deactivated, and the wheeled stretcher is removed from the procedure room.



Diacor Zephyr "x-series" Patient Positioning and Transfer System Workflow

Benefit: Setup and disassembly of the patient's immobilization and positioning devices can occur in a Set-Up Room. This decreases the time a patient occupies the Treatment Room and increases the time available to treat patients.

The Common Workflow

- ① First day in the clinic: The Zephyr base board is placed on an imaging table. The patient is placed on the Zephyr base board and immobilized in the treatment position. After the scanning/imaging takes place, the patient is removed from the immobilization devices and sent home until the first treatment day. In the meantime, the imaging data will be used to assist in radiation therapy treatment planning.
- ② Treatment Days 1 through n: In a Set-Up Room, the Zephyr base board is placed on a flat topped, "wheeled stretcher" (Device Product Code: FPO, Regulation Number 880.6910, Regulatory Class 1, 510(k) exempt). The patient is placed on the Zephyr and immobilized in the treatment position utilized during imaging.
- ③ The patient is wheeled to the Treatment Room. The low-pressure blower is activated. While remaining on the Zephyr base board, the patient is transferred to the treatment couch where they are then treated.
- ④ After treatment, the low-pressure blower is activated and the patient and the Zephyr base board are transferred back to the flat-topped stretcher and wheeled back to the Set-up room to be removed from the immobilization devices and the base board.

SECTION

GENERAL DESCRIPTION

2

2.1 GENERAL

The Zephyr XL Patient Positioning and Transfer System is used to aid in the support, positioning, and transfer of a patient for procedures involving Magnetic Resonance Imaging (MRI), Computed Tomography Imaging (CTI), Positron Emission Tomography (PET) imaging, Diagnostic X-ray Imaging (DXI), Radiation Therapy (RT) treatment by Medical Linear Accelerator or Charged Particle Accelerator and other procedures requiring transfer of a patient.

2.2 FEATURES

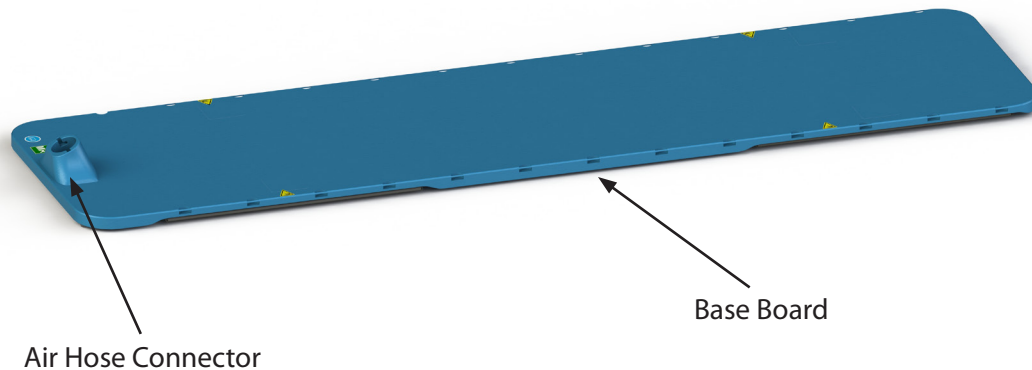


Figure 2.1 Zephyr XL Base Board Features

2.2.1 Patient Transfer Base Board

The Zephyr XL Patient Positioning and Transfer System consists of a rigid “MR Safe” Kevlar/Epoxy base board measuring 198.12cm x 53.01 cm x 2.54cm (including pads). The underside of the base board has four perforated lift pads.

2.2.1.1 Air Pads

Figure 2.2 shows the four air pads that provide lift to the Zephyr XL base board when the blower is on.

2.2.1.2 Air Hose Connection

The hose connector accepts the mating connector on the air hose. To attach the hose, it is only necessary to insert and twist the hose connector a partial turn to lock the hose to the sled. To remove the hose, lift the collar to release the lock, then twist the entire connector and pull the hose out.

2.2.2 Zephyr XL Air Blower and Hose



Blower must remain outside of the MR Suite. This blower is “MR Unsafe”. To remain connected, a longer hose is available upon request.

The Zephyr XL Patient Positioning and Transfer System utilizes forced air as a low friction bearing to transfer patients from one flat surface to another, eliminating the need to manually lift the patient. The forced air is provided by an accessory air blower through an extended length of flexible hose connected to the base board. The air is then routed to the perforated lift pads on the underside of the base board. A longer hose is available upon request to position the “MR Unsafe” blower unit outside an MR imaging room and continue to remain connected.

Note: The blower has an internal filter that needs to be replaced annually or when visibly dirty. Figure 2.3 shows the air blower and hose as well as important features of the blower.

2.2.2.1 Power Cord/Handheld Blower Control

The blower is operated using the Rocker Switch on the connected pendant controller. When the blower is plugged in and turned on, the blue light on the Rocker Switch indicates the operating status:

Light Signal	Indication	Recommended Action
Blinks Three Times	Ready for operation	Use the rocker switch to activate the air lift when ready.
Blinks Continuously	Blower plugged in and turned on while rocker switch was in activated position	Turn rocker switch to the OFF (down) position. Wait five seconds. Use the rocker switch to activate the air lift when ready.
No Light Signal	Blower not plugged in	Verify that the blower is connected to a functioning outlet.
Steady light, but rocker switch not activating blower	Blower not powered on	Verify that the button on top of the blower has been pressed to enable it.

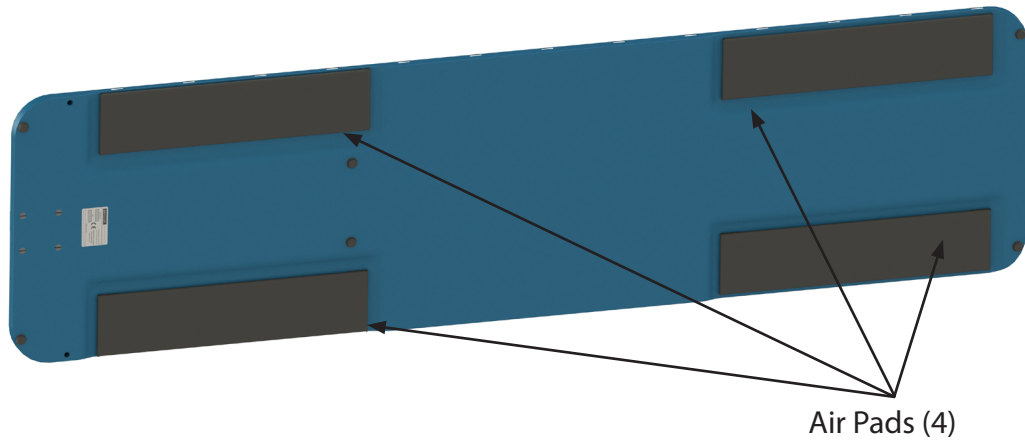


Figure 2.2 Bottom View of Zephyr XL Base Board

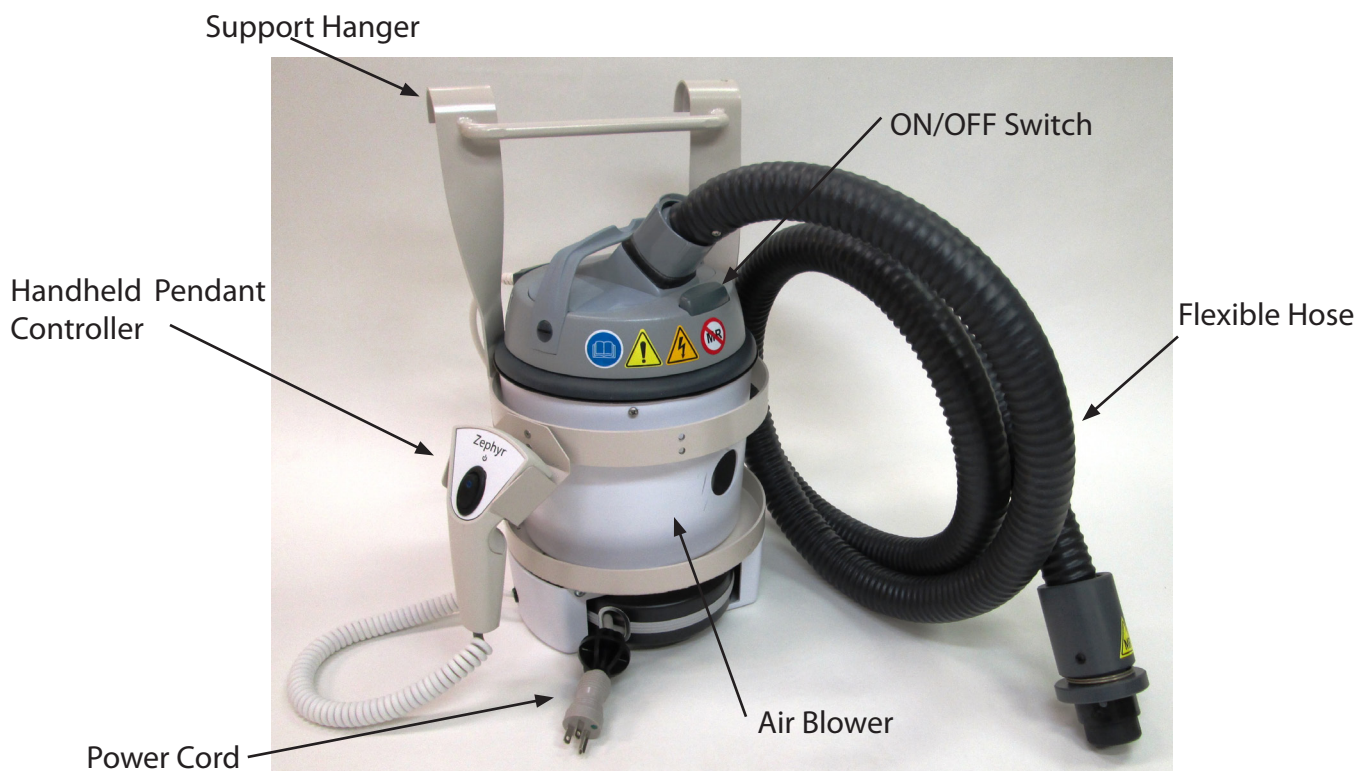


Figure 2.3 Zephyr XL Air Blower and Hose

2.2.2.2 ON/OFF Switch

The ON/OFF switch is a push to connect/push to disconnect power switch. The switch must be in the ON position to enable the Handheld Blower Control to control the power of the Zephyr XL blower.

2.2.2.3 Flexible Hose

A flexible hose carries the air from the Zephyr XL air blower to the base board. A ten (10) foot hose is supplied with the Zephyr XL blower. If requested a longer hose is available. A longer hose may be needed when used for MR imaging.

2.2.2.4 Quick Turn Hose Connection

A quick turn connector attached to each end of the flexible hose connects to both the air blower and the base board.

UNPACKING, INSTALLATION, USE

3.1 GENERAL

The Zephyr XL is designed ready for installation following removal from its packing container.

3.2 UNPACKING AND INSPECTION

When the Zephyr XL arrives, inspect all shipping containers for evidence of physical damage. If there are any dents, scratches or other evidence of physical damage to the boxes, note the damage on the shipper's copy of the bill of lading and file a claim against the shipper.

In the case of shortages or malfunctions, notify Diacor immediately to arrange for replacement or repair. Refer to sections 5.3 for the discussion of replacement or repair of products under warranty. Save all packing containers and materials for the Zephyr XL in the event it needs to be returned to Diacor for replacement or repair.



Caution

Always use two people when lifting the base board to or from any flat surface.

3.3 INSTALLATION

Using two people, place the base board on a flat table top or stretcher(see above caution). The four air pads should be resting on the surface of the flat table top or stretcher.

Connect the blower air hose to both the connector on the base board as well as the connector on the air blower. This requires only a partial turn clockwise. Plug the electrical cord from the air blower into a power outlet. Verify that the power switch is turned off and the Pendant Rocker Switch is turned off.

3.4 USE



WARNING

Do not allow the sheet or pad to slide underneath the base board as it is important that the users know exactly where the base board is on the flat table top. Failure to control the sheet or pad may cause the base board to lift incorrectly or to catch the sheet or pad under the base board.

Prior to each use the base board must be cleaned by the standard requirements of the user that fall under "any product that may come in contact with a patient." Next, if applicable, cover the base board with a sheet or a sterile pad to protect the patient, following the standard setup for the procedure. Do not allow the sheet or pad to slide underneath the base board as it is impor-

tant that the users know exactly where the base board is on the flat table top. Failure to control the sheet or pad may cause the base board to lift incorrectly or to catch the sheet or pad under the base board.

The base board is capable of attachment of various commercially available patient support and positioning accessories utilized for imaging and treatment.

The base board is now ready for placement of positioning aids, if required, and ISO ready for the patient. The positioning aids, if required by the user, are placed upon and attached to the base board. The patient is then positioned on the base board and immobilized as per physician's instructions.

The patient is transferred to the required position by activating the blower. On the air blower, ensure that the power switch on. Flip the Pendant Rocker Switch toward the blue light to initiate the air flow. As the blower supplies air to the lift pads, the pads generate a nominal lift of 1 centimeter to the base board. This lift enables the base board to be moved from one flat surface to another with ease by two persons. Adjust the lift with the variable power control. The medical staff guides the base board and the patient to the position desired.

The base board is aligned with the index locations if available in the table. The blower is then deactivated and the base board settles on the flat supporting surface. The patient is then imaged or treated as required. During the procedure, the base board will function as an accessory aid to support and position the patient, utilizing any non-Diacor positioning aids required by and supplied by the medical staff. After the procedure, the blower is activated and the base board and patient are transferred to the wheeled stretcher. The blower is deactivated and the wheeled stretcher is removed from the procedure room.



Caution

It is extremely easy to move a patient that has been lifted by the air pads. However, for safety purposes, two people must assist in moving the patient whenever the base is supported by the air pads.



WARNING

There are no stops at either end of the flat table top. It is important that the users control the base board as it is moved to the extreme ends of the flat table top and prevent it from extending over the flat table top. The patient should not be moved on the base board with the air pads inflated at the same time that the table is moving.

3.4.1 Pinch Points



Caution

Prevent pinched fingers. Whenever the Zephyr XL base board is elevated by the air pads, it is possible for the users or the patient to allow their fingers to go underneath the base. When the blower is turned off, the base board will lose its lift and may pinch fingers that are beneath it.

SECTION SERVICING

4

4.1 GENERAL

The Zephyr XL requires careful handling and cleaning following each use but generally requires minimal service.

4.2 CLEANING

The Zephyr XL makes noncritical patient contact, but these contact areas must be thoroughly cleaned following each use to prevent spread of infection by contact.

4.2.1 Cleaning Method

After each use, wipe the surfaces of the base board with wipes containing a mild cleaning and disinfecting solution of 14% alcohol and active quaternary ammonium chlorides or a similar disinfecting solution. (One such solution is offered by Professional Disposables International with a trade name of SANI-CLOTH® PLUS). After the cleaning process is complete, let the cleaned surfaces air dry. Do not use water as either a cleaning or rinsing agent. Never use aerosol cleaning sprays, cleaning agents, solvents or abrasive detergents.

4.3 PERIODIC MAINTENANCE

Diacor recommends inspecting the base board monthly for broken or non-functioning parts. Contact Diacor for replacement parts. See section 5.3. Replace the plastic hose cover as needed.

4.3.1 Air Blower Filter

The filter in the Zephyr XL air blower should be cleaned or replaced annually or when visibly dirty. There are three screws that must be removed to separate the blower from the canister and allow access to the filter. The filter can be cleaned with water or replaced and the three screws returned to their original position. Filter replacements are available from Diacor.

4.4 HANDLING AND STORAGE

Handle the Zephyr XL carefully to prevent damage. Store in a safe place when not in use.

4.5 AIR PADS

Should an air pad be damaged, please contact Diacor for service. For contact information see section 5.3.

SECTION WARRANTY

5

5.1 GENERAL

The Zephyr XL is warranted by Diacor for a period of one (1) year from the date of shipment.

The Diacor warranty coverage is limited to defective materials or workmanship. The warranty is void if the Zephyr XL has been damaged by accident, unreasonable or improper use, neglect, or other causes not arising out of defects in material or workmanship.

5.2 WARRANTY DISCLAIMERS

The express warranty provided herein is in lieu of any and all implied warranties arising out of the sale of the Zephyr XL, including but not limited to the implied warranties of merchantability and fitness for a particular purpose. Diacor shall not be liable for loss of use of the Zephyr XL or other incidental or consequential costs, expenses, or damages incurred by the customer or other users.

5.3 WARRANTY PERFORMANCE

During the stated warranty period, the Zephyr XL will be repaired or replaced, at the option of Diacor, Inc., with a new or reconditioned Zephyr XL when the units are returned shipping prepaid to Diacor, Inc., 2550 Decker Lake Blvd., Suite 26, Salt Lake City, Utah 84119. Please contact Diacor, 800-342-2679 or 801-467-0050, for a Return Material Authorization (RMA) prior to sending the defective unit back. The replacement of a Zephyr XL will not extend the expressed warranty stated herein beyond the original warranty period.



TECHNICAL INFORMATION

6.1 GENERAL

6.2 SPECIFICATIONS

Weight	28 lb. 12.7 kg.
Length	78 in. 198.12 cm.
Height (with pads)	1 in. 2.54 cm.
Width	20.87 in. 53.01 cm.
Maximum Patient Weight	450 lb. 204 kg.

Non-clinical testing was completed under the following conditions:

- Static Magnetic Field: 1.5 to 3 Tesla
- Spatial Gradient Field: 4.5 Gauss/cm (45 mT/m) max.
- Maximum Whole Body Averaged Specific Absorption Rate (SAR): 1.1 W/kg for 10 minutes of scanning.
- Temp Rise at Max. Whole Body Averaged SAR of 1.1 W/kg: 0 °C

This testing has demonstrated the Diacor Zephyr XL Patient Positioning and Transfer Base Board is MR Safe.



Caution

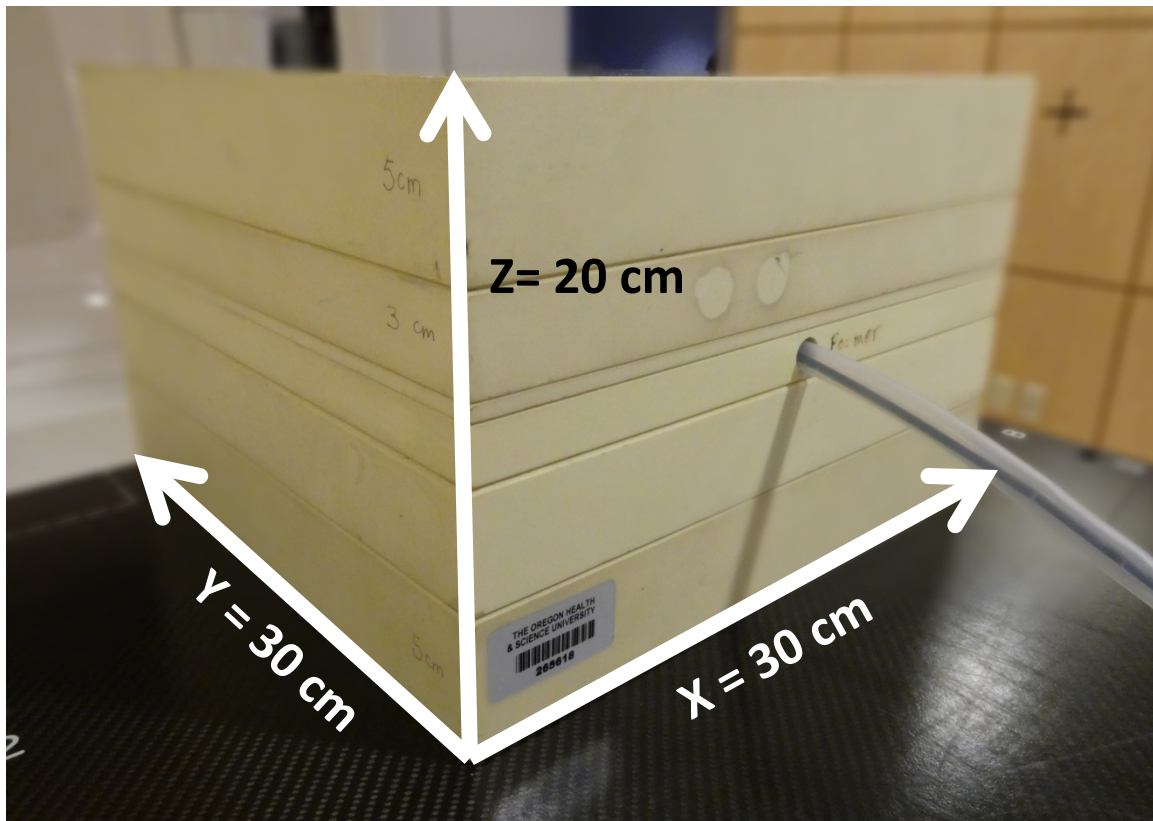
Blower must remain outside of the MR suite. This blower is “MR Unsafe”. To remain connected, a longer hose is available upon request.

6.3 DIACOR BASEBOARD ATTENUATION MEASUREMENTS

Diacor Baseboard

Attenuation Measurements

Equipment: Solid Water Phantom



Equipment: Farmer Chamber

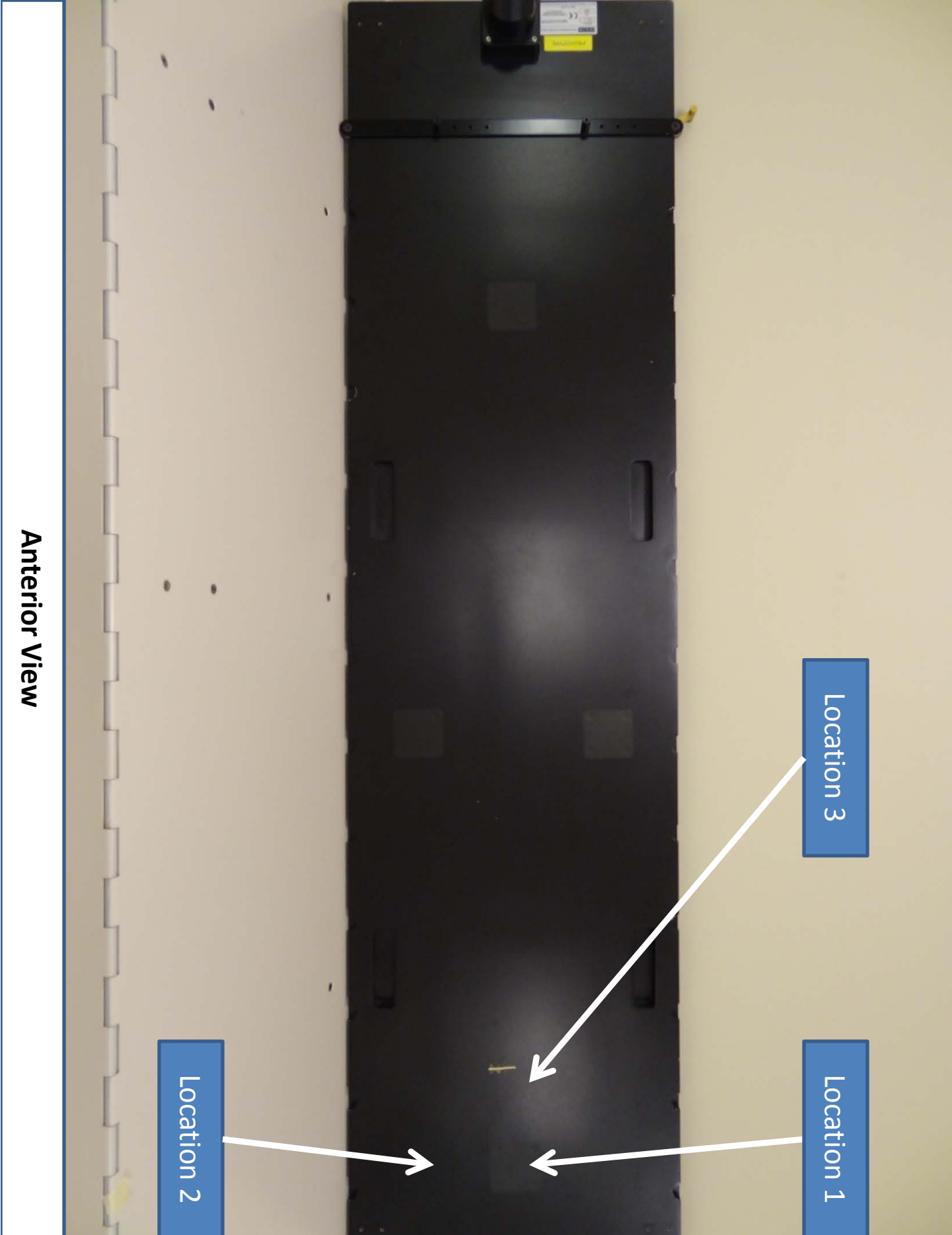


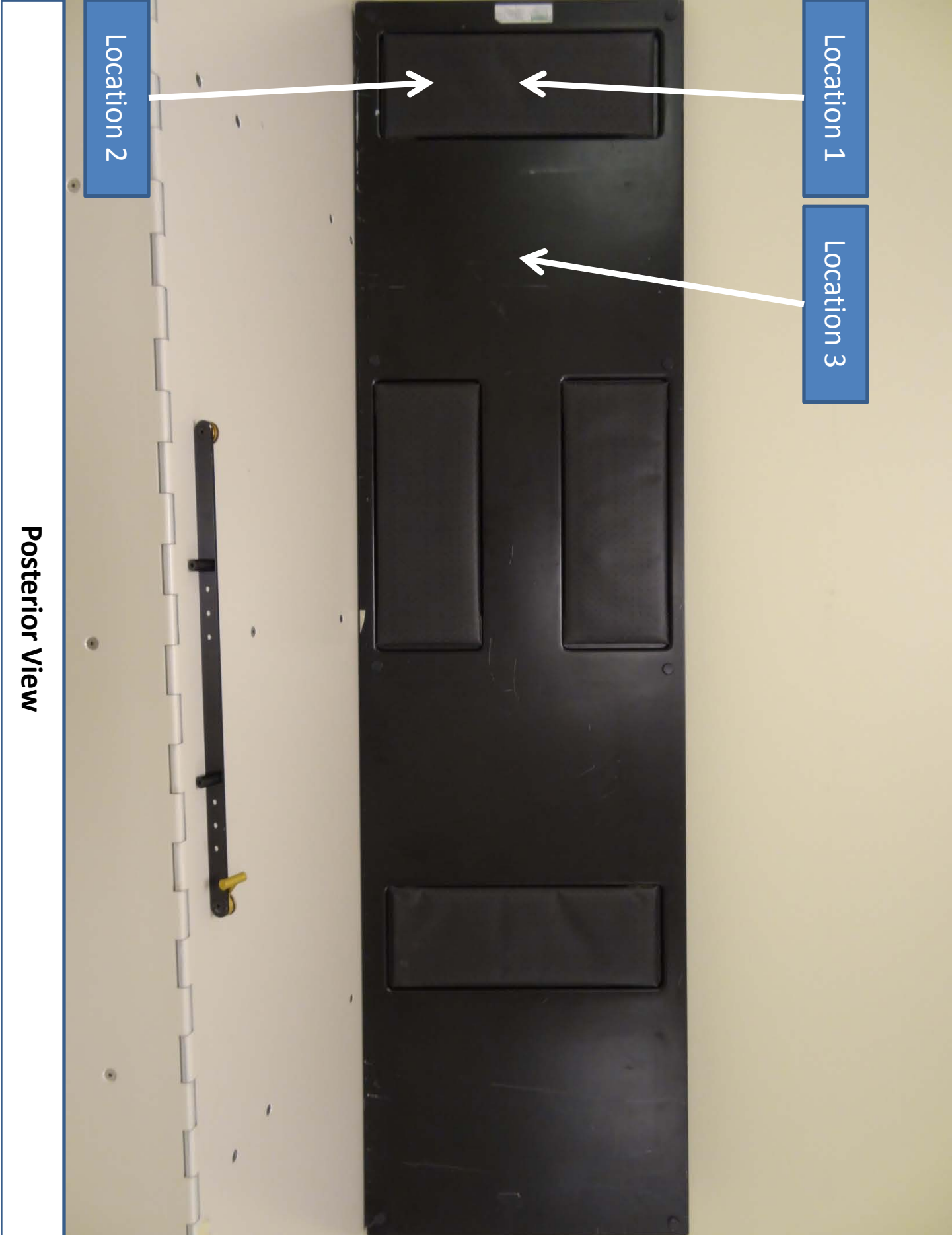
Equipment: Electrometer



General Setup in the Presence of the Diacor Baseboard







Diacor Baseboard Attenuation Measurement: Static			Diacor Baseboard Attenuation Measurement: Arc		
Setup Parameter and Equipment					
Chamber Type	FC65-G (Farmer)	Chamber Type	FC65-G (Farmer)		
Chamber Serial Number	730	Chamber Serial Number	730		
Chamber Leakage	0	Chamber Leakage	0		
Chamber Calibration	28-Dec-10	Chamber Calibration	28-Dec-10		
Electrometer Type	Unidose-E	Electrometer Type	Unidose-E		
Electrometer Serial Numbe	00499	Electrometer Serial Numbe	00499		
Electrometer Calibration	3-Jan-11	Electrometer Calibration	3-Jan-11		
Phantom	Solid Water	Phantom	Solid Water		
Phantom Dimension	X = 30 cm Y = 30 cm Z = 20 cm	Phantom Dimension	X = 30 cm Y = 30 cm Z = 20 cm		
SSD	90 cm	SSD	90 cm		
Field Size	10 cm X 10 cm	Field Size	10 cm X 10 cm		
Chamber Depth	10 cm	Chamber Depth	10 cm		
MU	200	MU	200		
Energy	10 MV	Energy	10 MV		
DR	600	DR	600		
Diacor Base Board on top of solid water phantom when needed		Diacor Base Board on top of solid water phantom when needed			
Measurements					
Location 1: Bladder with Hole		Location 1: Bladder with Hole			
AF	0.5%	AF	3.0%		
Location 2: Bladder with no Hole					
AF	3.3%				
Location 3: Solid Board		Location 3: Solid Board			
AF	1.7%	AF	1.4%		

Diacor Baseboard Attenuation Measurement: Static	Diacor Baseboard Attenuation Measurement: Arc
Setup Parameter and Equipment	

Chamber Type	FC65-G (Farmer)	Chamber Type	FC65-G (Farmer)
Chamber Serial Number	730	Chamber Serial Number	730
Chamber Leakage	0	Chamber Leakage	0
Chamber Calibration	28-Dec-10	Chamber Calibration	28-Dec-10
Electrometer Type	Unidose-E	Electrometer Type	Unidose-E
Electrometer Serial Number	00499	Electrometer Serial Number	00499
Electrometer Calibration	3-Jan-11	Electrometer Calibration	3-Jan-11
Phantom	Solid Water	Phantom	Solid Water
Phantom Dimension	X = 30 cm Y = 30 cm, Z = 20 cm	Phantom Dimension	X = 30 cm Y = 30 cm, Z = 20 cm
SSD	90 cm	SSD	90 cm
Field Size	10 cm X 10 cm	Field Size	10 cm X 10 cm
Chamber Depth	10 cm	Chamber Depth	10 cm
MU	200	MU	200

Energy	6 MV	Energy	6 MV
--------	------	--------	------

DR	600	DR	600
----	-----	----	-----

Diacor Base Board on top of solid water phantom when needed	Diacor Base Board on top of solid water phantom when needed
---	---

Measurements

Location 1: Bladder with Hole	Location 1: Bladder with Hole
-------------------------------	-------------------------------

AF	1.1%	AF	3.8%
----	------	----	------

Location 2: Bladder with no Hole	
----------------------------------	--

AF	4.4%
----	------

Location 3: Solid Board	
-------------------------	--

AF	2.1%
----	------

Location 3: Solid Board	
AF	1.7%

Diacor Baseboard Build-up Measurement: Static

Date: 11/12/2012

Setup Parameter and Equipment

Chamber Type PTW Advanced Markus Plane Parallel Chamber
 Chamber Serial Number TN34045
 Chamber Leakage 0
 Chamber Calibration Not Applicable
 Electrometer Type Unidos-e-E
 Electrometer Serial Number 00499
 Electrometer Calibration 3-Jan-11

Phantom Solid Water
 Phantom Dimension X = 30 cm Y = 30 cm Z = 20 cm
 SSD 100
 Field Size 10 cm X 10 cm
 Chamber Depth Variable
 MU 100

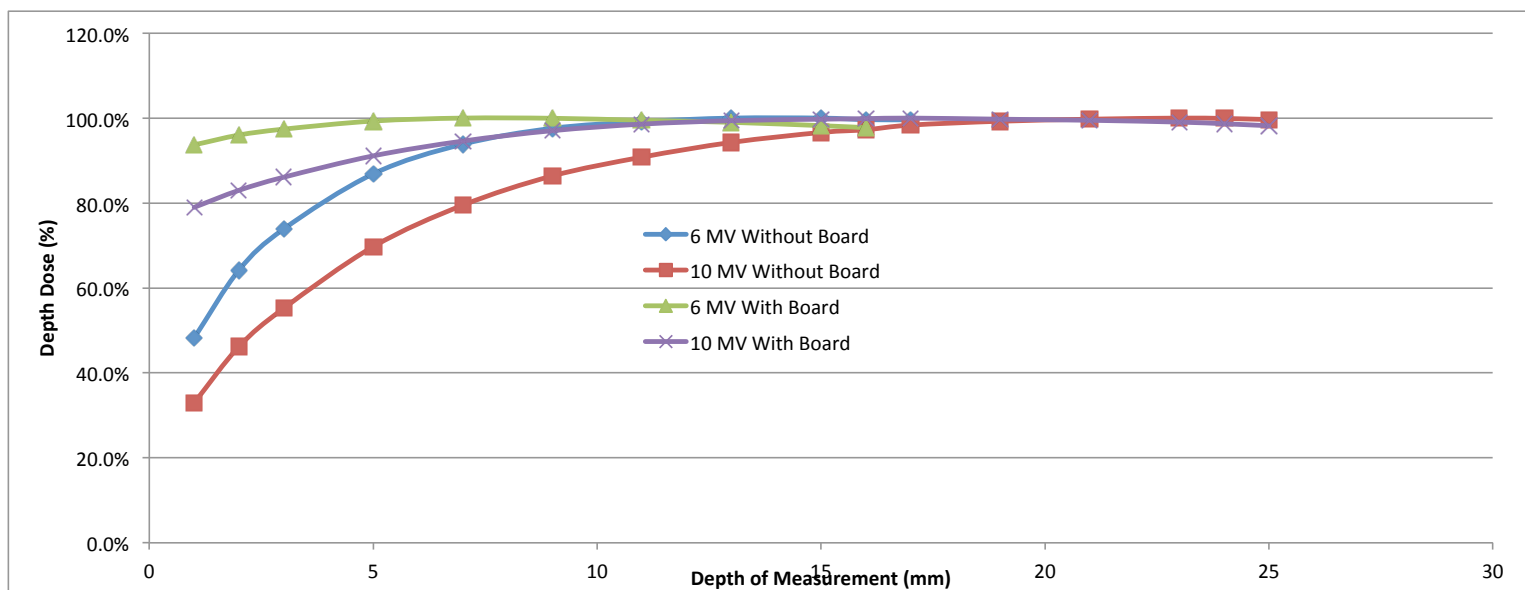
Energy 6 MV and 10 MV
 DR 600 MU/Min

Diacor Base Board on top of solid water phantom when needed

Depth of

Measurement

in mm	Raw Readings Without Board		Raw Readings With Board		Dose Relative to Dmax Without Board		Dose Relative to Dmax With Board	
	6 MV	10 MV	6 MV	10 MV	6 MV Without Board	10 MV Without Board	6 MV With Board	10 MV With Board
1	0.366	0.253	0.719	0.613	48.2%	33.0%	93.7%	79.0%
2	0.487	0.355	0.737	0.644	64.2%	46.2%	96.0%	83.0%
3	0.561	0.424	0.748	0.668	73.9%	55.2%	97.4%	86.1%
5	0.660	0.536	0.763	0.707	86.9%	69.7%	99.3%	91.1%
7	0.713	0.611	0.768	0.734	93.9%	79.5%	100.0%	94.6%
9	0.741	0.664	0.768	0.753	97.6%	86.4%	100.0%	97.0%
11	0.753	0.698	0.764	0.765	99.2%	90.8%	99.5%	98.6%
13	0.759	0.725	0.760	0.771	100.0%	94.3%	99.0%	99.4%
15	0.759	0.743	0.754	0.774	100.0%	96.6%	98.2%	99.7%
16	0.757	0.748	0.751	0.775	99.6%	97.3%	97.7%	99.9%
17	0.756	0.756		0.776	99.6%	98.4%		100.0%
19		0.763		0.774		99.3%		99.7%
21		0.767		0.772		99.7%		99.5%
23		0.769		0.769		100.0%		99.1%
24		0.768		0.766		99.9%		98.7%
25		0.766		0.762		99.7%		98.2%



Warning: Materials in the Zephyr XL have been measured and determined to be approximately 6mm tissue equivalent for both 6MV and 10MV. As these measurements are machine and energy dependent each site must make their own measurements before using.

